

Libby Asbestos Superfund Site Toxicological Data Gaps

Superfund/ORD Asbestos Research Needs Meeting
Research Triangle Park
January 17-18, 2007

Libby Team
USEPA Region 8

Discussion Points

Cancer Slope Factor (CSF)

Draft OSWER Interim Risk Methodology

Reference Concentration (RfC)

Systemic Effects

Target Tissue Dosimetry

IRIS Cancer Slope Factor *Data Gaps*

Does not specifically consider the increased cancer potency of amphiboles

- Based mainly on occupational exposures to chrysotile
- Includes data from a few occupational studies with mixed amphibole exposures

Does not account for the toxicity of short, thin fibers

Considers only exposures specific to occupational settings but does not address

- Exposures occurring in childhood
- Shorter duration, episodic exposures

Cancer Slope Factor *Data Needs*

Critical needs for the Libby Site

- Cancer slope factor for respirable fraction of Libby Amphibole
- Toxicity of subfractions of respirable portion of Libby Amphibole
 - Short/thin fibers
 - Focused analytical method development
- Less-than-lifetime exposures

Added value – comparative fiber toxicity

- Short-sighted not to address toxicity of other amphiboles and similar minerals in other Regions

Draft OSWER Interim Risk Methodology

Holds promise but extensive peer review and validation are necessary

Concerns arise from uncertainties associated with

- Historical epidemiological data
- Historical dose reconstruction
- Reconstruction of fiber size distributions for epidemiological studies

Lack of fiber size distribution data in epidemiological studies

Surrogate fiber size distributions developed from an independent set of studies and applied to epidemiological studies

Surrogate fiber size distribution data not directly extrapolable to epidemiological studies

Reference Concentration (RfC)

Data Gaps and Needs

Data gap

- No RfC currently available

Under construction

- Region 8 currently working on Libby-specific provisional RfC (Dr. Benson's presentation this afternoon)
- Based on fibrotic lung changes in historical worker cohort

Critical data need

- Identification/confirmation of critical effect
- Have we appropriately identified the critical effect? Are there other endpoints that are candidates for the critical effect?

Systemic Effects *Data Gaps and Needs*

Data gap

- Lack of complete database
 - Immune-mediated diseases
 - Chronic inflammation
 - Developmental and reproductive effects
- Necessitates use of an uncertainty factor for database limitations in development of the RfC

Critical data need

- Animal toxicity data that can aid in identification of systemic effects
- Reduced uncertainty in derivation of RfC

Target Tissue Dosimetry *Data Gaps and Needs*

Hazard Identification incomplete

- Effects on non-respiratory organs/tissues
- Inhalation and oral routes of exposure

Quantitative data on target tissue burdens of Libby Amphibole needed

- Informs the need for additional studies for complete hazard identification

Target Tissue Dosimetry *Data Gaps and Needs (cont.)*

- Uncertainties in quantitative dose-response relationship
 - Historical dose reconstruction from epidemiological data
- Improved quantitative characterization of dose-response relationship is needed
 - Appropriate internal dose metric
 - Internal inhaled dose metric & normalizing factor
 - Time course data (fiber retention)
 - Improved scientific basis for dose-response value
 - Reduces uncertainty and improves risk assessment

Reduced uncertainty



More accurate risk assessment



More effective cleanup

Many thanks to OSWER and ORD
for making this meeting possible,
and to all who have participated.

- The Region 8 Libby Team